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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/432,469	11/03/1999	SCOTT L SULLIVAN	SUL-3-2-001	1066

7590 10/08/2002
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EXAMINER

LE, THIEN MINH

ART UNIT	PAPER NUMBER
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2876

DATE MAILED: 10/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/432,469

Applicant(s)

SULLIVAN ET AL.

Examiner

Thien M. Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,12 and 40-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,12,40-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- ☐ Interview Summary (PTO-413) Paper No(s). ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The response filed on 7/11/2002 has been entered. Claims 1-3, 5-10, 12, and 40-50 remain for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-10, 12, 40-50 rejected under 35 U.S.C. 103(a) as being unpatentable over Ackley (Ackley - 4,266,478) in view of Kraft et al. (herein after Kraf - 5,502,944), Shamir (Shamir - 5,118,369) and Stafford et al. (hereinafter Stafford - 5,482,008).

Ackley ('478) acknowledges the need for printing information on the surface of a pill. According to Ackley, it is common practice to imprint an indicia over the surface of the capsules during the processing of capsules. The indicia, for example, could be the name of the manufacturer or of the name or batch number of the material packaged within the capsule or other information required by the Food and Drug Administration or other agencies. This can be done by "spin printing" an elongated indicia on the capsule or by printing the capsule in another suitable manner. Spin printing is accomplished by causing the capsule to spin about its axis as the indicia is imprinted upon the surface of the capsule.

The capsules may be uniformly oriented or rectified prior to reaching the imprinting station whereby the capsules can be uniformly rotated during the imprinting operation. The rotation occurs in a manner which allows rotation of the capsule without substantial slippage between the imprinting head and the capsule surface whereby a sharp, precise, printed indicia can be produced on each capsule as it passes through the imprinting station.

However, Ackley fails to disclose the method of printing a bar code on a pill for automatic product identification purposes; wherein the bar code contains information relating to the pill.

Kraft et al. (herein after Kraft – 5502944), on another hand, discloses a medication dispenser system. According to Kraft, the system comprises a medications database which contains the NDC code for the medication, the manufacturer, the brand name, the generic name, the dosage form, the location of the drug in the pharmacy, etc. and pricing information. For each medication ordered for a patient, the pharmacy system maintains a database of the medication ordered, the frequency of administration, start and stop dates (and times) for administration, and the nursing station to which the medication should be delivered.

Kraft discloses a subsystem 44 comprising two optics systems, singulation optics 124 and a container identification optics 126. The container identification optics 126 may comprise, for example, a bar code or a block code scanner. The container identification optics 126 reads a label disposed on the outside of each container which identifies its contents. The contents (as defined by the label) of a chosen container is compared with the specified medication in order to verify that the correct medication is being dispensed. The container identification optics, in conjunction with the control electronics, also determines whether the medication in the module has reached its expiration date.

Kraft also discloses the use of a label 144 containing information on the medication stored within container 130. This information is used for the database

internal to the dispenser 12 and for verification prior to dispensing medication. The label 144 can take a variety of formats, such as one of a number of bar codes or block codes.

Shamir (Shamir - 5,118,369) discloses a microlabelling system and process for making microlabels. Shamir teaches both the method making microlabels and the method for using these labels to provide a unique system for identifying an integrated circuit (IC) die on a wafer. The label has the size of 2 X 2 mm. The microlabels can be either color bar or black/white coded. The labels can be used to encode information relating the IC. Shamir further discloses that the microlabels may be utilized in any application in which product identification requires exceedingly small labels.

Stafford et al. (hereinafter Stafford - 5,482,008) discloses a bolus 9 having inner core 2. According to Stafford, the inner core 2 comprises plastics material surrounding an electronic transponder 4, which may conveniently be a cylindrical transponder with a diameter in the range of 2-5 mm, and a length in the range of 15-35 mm (wherein the dimension would also embrace the size of the typical capsule and/or pill). A permanent visual representation 11 of an identification code is carried on the external surface of the inner core 2. The visual representation comprises a bar code 15 and a numeric code corresponding thereto. The visual representation label may be printed directly into the exterior surface of the inner core, for example by inkjet printing.

It would have been obvious to print a bar code for identifying information relating to the pill on the surface of the pill. Reference to Kraft is cited as evidence that there

are plenty of information relating to the pill which could be of interest or necessity to a user. Kraft is also disclose the need of product identification including the use of bar codes, bar codes readers, databases, etc. Reference to Shamir is cited as evidence showing it is possible to use of a micro-bar code to label small product other than an IC die/chip. Reference to the Stafford is further cited as evidence showing that it is actually possible to print a bar code on the surface of an object having the approximate shape of a typical pill and/or capsule. From the comprehensive teachings of the prior art of record, it has been determined that it would have been obvious to provide a bar code on the surface of the pill for the purpose of produce identification thereof. The modification is well within the skill levels and expectations of an ordinary skilled artisan at the time the invention was made.

Regarding claim 3, see the discussions above. Specifically, Stafford disclose the concept of having a transparent cover for protecting the inner core 2 and the bar code 15 for being damaged. Following this teaching, it would have been obvious to incorporate the use of a protective layer for protecting the surface of the pill and the bar code from being damaged. The modification is merely a design consideration which would have been well within the skill levels and expectations of an ordinary skilled artisan.

Regarding claim 6-10, 12, 40-50, see the discussions above. Specifically, the various features of the claims, i.e. 2D bar code, PDF 47 bar code, UPC bar code, the step of administering the drug to a user, the step of warning a user based on dosage information, etc. are merely the variations in designs and/or intended applications of a

pill product identification system. Without any specific, unexpected result, it would have been obvious to incorporate these features in the system as taught, and as has been discussed above. The modifications are merely within the skilled level and expectations of an ordinary skilled artisan.

Response to Arguments

Applicant's arguments filed 7/11/2002 have been fully considered but they are not persuasive.

Applicants argue that the examiner merely makes a "conclusory statement without making any reference to prior art teachings". Applicants then go on to separately analyze each statement of the Office Action in order to support their arguments. The examiner disagrees.

In the Office Action dated 4/8/2002, the examiners cited 4 references including one primary reference and three supporting references for his grounds of rejection on the claim. The examiner also provides a statement for each reference in order to establish the scope and contents of these cited prior art references. The difference between the teachings of the prior art of record and the claimed invention is clearly stated. The motivation statements are also included to establish the reasons why each supporting reference is being used in supporting the proposed combination. For these reasons, the examiner disagrees with applicants' statement that the examiner's obvious statements set forth in the Office Action is merely a "conclusory statement".

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In the Office Action, the primary reference (Ackley), is cited as evidence showing the needs for marking pills. Though Ackley is silent about the use of a bar code to label a pill, the missing feature is strongly suggested and evidenced by Kraft, Shamir, and Stafford.

Specifically, the examiner first cited Kraft as evidence showing that a bar code could be used to in place of the printed indicia on the pill as taught by Ackley. Reference to Shamir, and Stafford are both cited as evidence showing that labeling an object with the size and shape of a pill is possible. Specifically, Shamir discloses a 2D bar code and discloses that the bar code could be used to label any small object (which of course include a pill, or a capsule). Reference to Stafford is cited as evidence showing the use of bar code for labeling a capsule shaped object (i.e., the transponder as cited in the Office Action). According to the examiner, the Office Action not only citing that there are real need to label the pills, the capsule; but also providing evidence that more information (in the form of a bar code) could be printed on the surface of the pills or capsules.

With respect to applicants' arguments, the examiner respectfully submits that the differences between the claimed invention and the prior art should not be viewed and considered as separate statements and assertions; but should be as a whole with respect to what they suggest to one of ordinary skill in the art.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), requires that the examiner to consider the following steps while establishing non-obviousness grounds of rejection.

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

From the Office Action, the examiner clearly establish the scope, content of the prior art as well as citing the difference between the cited prior art and the claimed invention. The steps of resolving the level of an ordinary skill in the art and considering the objective evidence of the cited references have been clearly suggested by the examiner in the grounds of rejection.

Hence, the examiner is of the view that applicant's assertions and arguments are based on piecemeal analyses which fail to consider the examiner's grounds of rejection as a whole.

For the reasons set forth above, the examiner respectfully maintains the grounds of rejection set forth in the Office Action dated 4/8/2002. With regard to claims 6-10, 12, 40-50, since applicants have not argued the specific of the claims, the grounds of rejection on these claims are respectfully maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thien M. Le whose telephone number is (703) 305-350. The examiner can normally be reached on Monday - Friday from 7:30am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on (703) 305-3503. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 308-5841 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.



Le, Thien
Primary Examiner
Art Unit 2876
September, 10, 2002